



Buyer Beware

OIG shines a spotlight on provider relationships with long term care pharmacies and scrutinizes contract pricing structures.

IN NOVEMBER 2009, OMNICARE, the nation's largest long term care pharmacy provider, agreed to pay \$98 million to settle several claims under the federal anti-kickback statute and the False Claims Act (FCA), including claims that the company provided consulting services to long term care facilities at prices below cost and below fair-market value to win pharmaceutical contracts. The settlement came one year after the Department of Health and Human Services' Office of Inspector General (OIG) published its "Supplemental Compliance Program Guidance for Nursing Facilities," cautioning that free goods and service arrangements, such as "pharmaceutical consultant services, medication management, or supplies offered by a pharmacy," are suspect and warrant careful scrutiny.

Heightened Scrutiny

The Omnicare settlement and the OIG guidance suggest that the relationships between long term care facilities and pharmacy providers will likely be subject to increased government oversight and enforcement in the near future, resulting in a need to revisit pricing structures.

The anti-kickback statute prohibits the knowing and willful offer, payment, solicitation, or receipt of goods or services of value in order to reward or induce the purchase of goods or services

paid for by a federal health care program. According to the whistle-blower, a former employee of Omnicare, the company violated the anti-kickback statute by offering pharmacy consultant services at below-market rates, which

the government later alleged were also below cost, to long term care facilities to induce them to enter into contracts allowing the company to provide drug products to patients and to bill Medicare, Medicaid, and other payers. The

SAFE HARBOR PROTECTIONS

Providers that contract with pharmacies can take some immediate steps to gird against the storm of intensified scrutiny imposed by the Office of Inspector General. Such facilities should attempt to structure their contracts to meet one of the anti-kickback statute "safe harbors"—statutory and regulatory provisions that provide protection from penalty or liability. One such safe harbor is the personal services and management contracts safe harbor, which requires the following:

- The agreement is in writing and signed by the parties, with a term of at least one year;
- The full scope of the services or items being purchased is described in the agreement and does not exceed services that are reasonably necessary for the underlying business purpose;
- The compensation paid and received by the parties is set in advance and consistent with fair market value in an arms-length transaction; and
- The compensation is not related in any manner to the volume or value of federal health care program business between the parties to the contract.

Special rules apply for part-time services, which require that the agreement

specify the schedule of the part-time services, the precise length of each time period in which the services will be provided, and the exact charge for each time period.

Although meeting a safe harbor is the best protection, it is not necessary. Arrangements can instead satisfy a "facts or circumstances" test showing that they do not have an improper purpose to induce inappropriate referrals from one party to another. To satisfy such a test, parties should strive to meet as many elements of the personal services and management contracts safe harbor, or other safe harbor, as possible, in particular the requirement that the compensation be fair market value.

Pharmacies' costs for providing consulting services should be part of the analysis in setting prices for such services. This cost assessment may take into account what consulting services the pharmacies are providing to long term care facilities in comparison to what services are merely incidental to the pharmaceutical products the pharmacies are providing to residents.

Once an arrangement is set, it is important for the parties to abide by and enforce its terms.

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whistle-blower alleged that this practice was used by Omnicare in connection with obtaining pharmacy services contracts with thousands of facilities.

The claim was filed in 2002 under the FCA, which allows *qui tam* relators—also referred to as whistle-blowers—to bring actions on behalf of the government.

The government intervened in the relator's claim and consolidated four other pending cases against Omnicare in 2009, resulting in the multi-million dollar settlement.

Citing OIG's 2008 guidance, the settlement agreement stated that the "consultant pharmacist services contracts between Omnicare and nursing homes implicated the anti-kickback statute because, *inter alia* [among other things], they involved the provision of services at below cost and/or below fair market value."

In addition to the settlement agreement, Omnicare entered into a corporate integrity agreement (CIA), which provides for a contracts database and process for setting the terms of new arrangements, new policies and procedures, training, and other compliance program requirements, as well as a federal monitor to oversee the company's compliance activities and new contractual arrangements.

A Ripple Effect

The allegations in the complaint and the settlement agreement reflect the application of long-standing theories of the government.

In 1999, OIG took the position in two advisory opinions that the provision of below-cost services can be a form of improper inducement under the anti-kickback statute.

Given this climate, service contracts

and other financial arrangements within the long term care facility and pharmacy provider industries are likely to be an area of continued focus of government enforcement agencies.

Indeed, in the wake of the Omnicare case, prosecuting U.S. Attorney Michael Loucks declared that the settlement "provides a strong message to [long term care] pharmacies, as well as to pharmaceutical companies and nursing homes, that the government will not tolerate the payment of kickbacks [that] can distort proper medical judgment and put profits ahead of good medical care."

Moreover, by targeting the largest long term care pharmacy provider, the government may achieve a ripple effect in the market. Pursuing high-visibility providers in an effort to change industries is a tactic previously used by the government.

Over time, the Omnicare case could have the effect of changing the market rates that pharmacy providers charge for consulting services so that, at a minimum, those charges reflect the pharmacy's cost of providing the consulting services.

Indeed, some facilities that obtain

pharmacy services from Omnicare have already seen price increases for pharmacy consulting services, since, as required under its CIA, Omnicare reviewed its agreements and determined that pricing for certain of its consulting services contracts had to be increased to ensure compliance with the anti-

kickback statute. If parties choose to ignore this warning shot regarding free or below-cost pharmacy consulting services, pharmacies are not the only entities at risk of enforcement actions.

Reevaluate Relationships

Long term care facilities that receive such consulting services from pharmacies are equally at risk of enforcement actions themselves, as the anti-kickback law applies to both the giver and receiver.

To date, the government has not brought charges against the facilities that had consulting relationships with Omnicare before the settlement, but it is unclear whether *qui tam* relators have filed complaints under the FCA, as such complaints are often sealed.

Another set of allegations in the Omnicare case is similarly illustrative of the risks to long term care facilities. The government also pursued claims against both Omnicare and two nursing facility chains, alleging that Omnicare offered improper cash payments in order to induce the companies to sign long-term, 15-year pharmacy agreements. The two nursing facility companies and some of their principals, as individuals, settled with the government for \$14 million in February 2010.

Given this new climate, long term care facilities and pharmacy providers should reevaluate their relationships and revise their agreements.

The government's position in the Omnicare matter means that both long term care facilities and pharmacies must not only ask the question, "What is the going rate for this service in our area?" but must also consider whether the rates charged for consulting fees cover the pharmacy's cost of providing the services.

Facilities and pharmacies that do not move quickly to ensure that consulting pharmacy charges are consistent with fair-market value and the pharmacies' internal costs, risk being the focus of government enforcement and whistleblower actions in years to come. ■